Appln No.: 09/944,326
Amendment Dated: September 28, 2005
Reply to Office Action of July 28, 2005

REMARKS/ARGUMENTS

This is in response to the Office Action mailed July 28, 2005 for the above-captioned application. Reconsideration and allowance are respectfully requested

The Examiner objected to claims 14, 15 and 24 and rejected these claims under 35 USC § 112, second paragraph. Claim 14 has been canceled since the limitation therein was redundant given the specific recitation of Seq. ID No. 4. Claims 15 and 24 have been amended in view of the Examiner's remarks, and these amendments are believed to overcome the rejection.

The Examiner has rejected claim 19 for obviousness-type double patenting in view of claim 1 of US patent No. 6,900,167. Applicants respectfully traverse this rejection.

The purpose of the judicially-created doctrine of obviousness-type double patenting is two-fold. First, terminal disclaimers can be used to prevent the time-wise extension of patent terms through the filing of multiple applications. Since the advent of the twenty-year term, however, this is less significant. Furthermore, in this case, the cited patent has a term adjustment of 600 days, which means that absent an even longer extension in this case, any patent issuing on this application will expire first.

The second purpose of the doctrine of obviousness-type double patenting is to ensure that separate patents with claims that are obvious one over another do not issue and then end up owned by different parties, thereby increasing the burden on those who may wish to license the art. From this perspective also, the application of this doctrine makes no sense in this instance.

The claim of the issued patent relates to a specific species of modified oligonucleotide. This species has the same sequence as Seq. ID No. 4 of the present application but contains additional modifications. A separate application was filed because the specific modifications are not disclosed in this application. US Patent No. 6,900,167 issued first because it was allowed without an Office Action. In the Examiner's Statement of reasons for Allowance, however, it was stated that "the claims were interpreted as requiring the sequence with the specified modifications, as such this sequence could not be found in the art."

The PCT application corresponding to the original parent case, WO 00/49937, which discloses sequence ID No. 4 was of record in the prosecution of 6,900,167, and is cited on the cover of the patent. Given the Examiner's statement of reasons for allowance, and the absence of any rejection for double patenting, Applicants submit it was clear in that case that the Patent Office found that the presence of the modifications rendered the sequence independently patentable over the published disclosure of the sequence without the specific modifications.

This means that had an independent third party developed the specific modifications of the underlying sequence, a patent could have issued.

One purpose of the doctrine of obviousness-type double-patent is to prevent an inventor from gaining an advantage with respect to others because of the differences between art that can be cited in the two circumstances to support a certain § 102 and § 103 obviousness rejections. It is not intended, however, to place an inventor who continues to improve on his or her own work at a disadvantage as compared to a third party. The doctrine should not be invoked in a case where the earlier issued patent is patentable over the earlier disclosure when that disclosure is considered as prior art, even if the later issued patent may dominate the subsequent improvements. This is what the Examiner seeks to do here. Withdrawal of the obviousness-type double patenting rejection is therefore urged.

The Examiner also instituted a new rejection of claims 1 and 23 under 35 USC § 103 over Wong et al and EMBL accession number M63376 which disclose the sequence of human TRPM-2 but no antisense inhibition of TRPM-2, and Barrachini et al, which is a general teaching, unrelated to TRPM-2, that antisense compositions can be formulated for pharmaceutical use. Applicants traverse this rejection.

The Examiner states that it would have been obvious "to make an antisense oligonucleotide fully complementary to the sequence taught by Wong et al. ... and would contain the sequence identified as SEQ. ID NO. 4." As Applicants understand this statement, the Examiner is arguing that one could make a full length antisense construct that is 1350 bases in length, and because this would include the sequence which is sequence ID No. 4 that placing this construct in a pharmaceutical preparation would have been obvious. Claims 1 and 23 specify that the antisense used is an oligonucleotide. The term "oligonucleotide" is a term with an established meaning in the art that the Examiner has not considered when apparently asserting that a full length 1350 base cDNA can be considered an oligonucleotide. Oligonucleotides are **short** nucleotide sequences. For example, one web states

> Phrase: oligo
> Definition: oligo is an abbreviation of oligonucleotide, which is a short sequence of nucleic acids (generally fewer than 100 bases). Synthetic oligonucleotides are used, for example, as probes to detect the presence of a complementary DNA sequence.

http://www.tmbioscience.com/glossary.php, while others list differing, and generally shorter lengths, for example 25 bases or less. (http://www.biochem.northwestern.edu/holmgren/Glossary/Definitions/ Def-O/Oligonucleotide.html). The oligonucleotides disclosed in the present application have lengths of 18-21 bases. The Examiner has not explained why any

person skilled in the art would find a 1350 base sequence to be properly described as an oligonucleotide. As such, to the extent that Applicants understand the rejection, it is plainly in error.

Furthermore, while Wong et al. and the EMBL submission describe the sequence of TRPM-2 cDNA, they do not provide any functional role for the TRPM-2 protein. Indeed, they specifically state that this remains to be established. (Wong et al., Abstract). Merely being implicated in a physiological process is not enough to make a protein a legally obvious target for therapy, since it cannot be known whether the protein should be enhanced (if it is expressed as part of an effort by the body to counteract a disease) or inhibited (if it is a cause of the disease), or even if the expression is a consequence of the disease that offers no therapeutic opportunity.

For these reasons, Applicants submit that the claims of this application are in form for allowance. Such action is respectfully urged.

Respectfully Submitted,

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